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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/790,170 | 03/01/2004 | Lawrence E. Bertolucci | | 1017 |

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

| EXAMINER | |
|---|---|
| MANUEL, GEORGE C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/790,170 | BERTOLUCCI, LAWRENCE E. | |
| | Examiner | Art Unit | |
| | George Manuel | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## **DETAILED** ACTION

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Applicant's disclosure states the exact mechanism for each type of headache is not known. See paragraph [0002]. Applicant's assertion that a significant reduction in migraines and/or headaches has been observed when electrostimulation is provided to the P6 point on the wrist appears to be anecdotal and not causal. Firstly, the nerves on the wrist have a long path to the head and it does not seem reasonable to expect a device attached to the skin surface on the ventral side of the wrist to be capable of traversing the path to the specific brain location to switch the synapses required to relieve headache pain. Secondly, even if the nerves of the wrist could be stimulated to affect the nerves that affect headache pain, the stimulation waveforms of Fig. 2 and Fig. 3 don't seem plausible for blocking the nerves that are firing to reduce headache pain. To the contrary, such signals would appear to cause more pain by sending stimulating signals that would increase nerve firings and increase the pain felt by the patient.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruzdowich et al (U.S. Patent 6,178,352) in view of Lee et al (U.S. Patent 6,735,469) and further in view of Negishi (U.S. Patent 5,201,319).

Gruzdowich et al claim the same method as Applicant except for the purpose of moderating blood pressure.

Lee et al teach a headache is associated with high blood pressure.

Negishi teach a splitting headache occurs the moment a subject stands up is caused by the standing high blood pressure.

One of ordinary skill in the art would have found it obvious to use the method claimed in Gruzdowich et al to relieve a headache or a migraine because Lee et al and Negishi suggest that removing the malady of high blood pressure removes the pain of the associated headache or migraine type of pain, a splitting headache.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Response to Arguments***

Applicant's arguments filed 9/21/06 have been fully considered but they are not persuasive. Applicant's arguments and specification do not support the conclusion that acupuncture points that depend upon where a patient is experiencing pain correlate with operability or effectiveness of the electrostimulation. Further, the correlation between anatomical body parts (i.e., the wrist, hand and arm) to headache pain does not imply or associate the causation of the pain to be relieved by the body parts being stimulated with electrical stimulation. The assertion that pain occurring at one extremity of the body can be relieved by stimulating an acupuncture point at one or more different extremities of the body does not appear to supported by either the disclosed specification or applicant's arguments.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

The examiner does not consider high blood pressure to be the cause of a migraine or other type of headache, but rather to be associated or correlated with a migraine or other type of headache.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

George Manuel
Primary Examiner
Art Unit: 3762